LABEL REVIEW

Application Number: 20-924

Name of Drug: Cernevit -12 IV Multivitamins

Sponsor: Baxter Healthcare

Material Reviewed: February 11, 1999, draft labeling

Submission Date: February 11, 1999,

REVIEW:

The draft labeling submitted dated February 11, 1999, was sent in response to labeling recommendations FAXED to the Sponsor on February 1, 1999. The following revisions have been made as follows:

PACKAGE INSERT

1. Under **Description** Section:

   a. Paragraph 1, Line Three, the phrase *"single-dose amber vial"* should be revised to read, DRAFT LABELING

   Reviewer comment: The **Description** section of the package insert has been modified per FDA labeling recommendation from February 1, 1999 FAX to firm.

   b. In the **Description** section, Paragraph 2, line one, Baxter has deleted the phrase, DRAFT LABELING

   Reviewer comment: This change is a change recommended by Baxter. It was not one of the recommendations made in FDA's February 1, 1999 FAX. **THIS REVISION WILL NEED REVIEW BY REVIEWING STAFF.**

c. In the **Description** section, under Other Ingredients section. Paragraph 1, which reads [redacted] should be deleted." (Baxter's recommendation).

Reviewer comment: The FDA's February 1, 1999, Fax had recommended that the phrase *". . . following reconstitution with WFI."* should be changed to read [redacted]

BAXTER'S REVISION WILL NEED REVIEW BY THE REVIEW STAFF.

2. Under **Drug Reactions** Section:

a. The section should has been titled *"Drug Interactions"* and not [redacted]

Reviewer comment: The changed has been made per FDA recommendations made in the February 1, 1999 Fax.

b. In the second paragraph, first sentence which read *"Folic acid has been reported as unstable ... "*, now reads, [redacted]

Reviewer comment: The changed has been made per FDA recommendations made in the February 1, 1999 Fax.

3. **Pregnancy**
Pregnancy Category C:

The last sentence of this paragraph which reads *" The use of Cernevit™ -12 IV Multivitamins."* has been moved such that it is the first sentence of this paragraph. **BAXTER'S REVISION WILL NEED REVIEW BY THE REVIEW STAFF.**

4. **Dosage and Administration**

The designation *"USP"* has been deleted following [redacted] in the second sentence of paragraph one.

Reviewer comment: **BAXTER'S REVISION WILL NEED REVIEW BY THE REVIEW STAFF.**

5. **How Supplied** section

The word *"glass"* has been added to the phrase [redacted]

Reviewer comment: **BAXTER'S REVISION WILL NEED REVIEW BY THE DIVISION REVIEW STAFF.**

VIAL LABEL

1. The NDC number has been updated from 0338--869-60 to [redacted]
2. The vitamin name [redacted] has been replace with its abbreviation *"B_5"*.

CARTON LABEL:

1. The NDC number has been updated from 0338--869-60 to [redacted]
2. The vitamin name [redacted] has been replace with its abbreviation *"B_5"*.
3. The phrase *"Each vial contains"* on the front flap of the carton has been changed to [redacted]

Reviewer comment: **BAXTER'S REVISIONS WILL NEED REVIEW BY THE DIVISION REVIEW STAFF.**

[redacted]